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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,692	01/22/2002	Bruno Macchia	50203/015001	8279

35743 7590 11/18/2003

KRAMER LEVIN NAFTALIS & FRANKEL LLP  
INTELLECTUAL PROPERTY DEPARTMENT  
919 THIRD AVENUE  
NEW YORK, NY 10022

EXAMINER

LEWIS, PATRICK T

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 11/18/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/031,692

Applicant(s)

MACCHIA ET AL.

Examiner

Patrick T. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-7 is/are rejected.
- 7) ☒ Claim(s) 2 and 3 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Applicant's Response dated September 2, 2003*

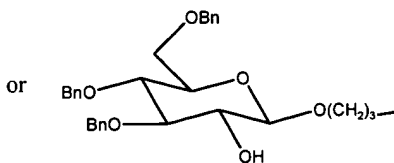
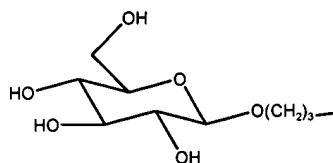
1. In the Response filed September 2, 2003, claim 1 was amended and claim 7 was added. Claims 1-7 are pending. An action on the merits of claims 1-7 is contained herein below.
2. The rejection of claims 1 and 4-6 under 35 U.S.C § 112, second paragraph, has been rendered moot in view of the amendments filed September 2, 2003.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 and 4-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds of formula (I) wherein R<sub>1</sub> or R<sub>2</sub> is

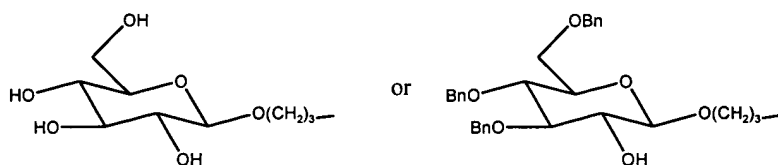


, does not reasonably provide enablement for compounds of formula (I) wherein R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, or R<sub>4</sub> is an alkyl or alkylene group with from 2 to 6 carbon atoms, linear or branched, unsubstituted or substituted with one or more saccharides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

A disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which it pertains to make and use the invention as of its filing date, *In re Glass*, 181 USPQ 31; 492 F.2d 1228 (CCPA 1974).

The instant specification is drawn to compounds of formula (I), a method for the preparing compositions comprising compounds of formula (I), and the use of same in a method for treating a tumor in a mammal. Compounds of formula (I) wherein R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, or R<sub>4</sub> is "alkyl or alkylene group with from 2 to 6 carbon atoms, linear or branched, unsubstituted or substituted with one or more...saccharides" lack support wherein applicants fail to provide a written description which teaches how to make and use same in the instant process for preparing a pharmaceutical composition or where applicants fail to teach how to use same to treat a tumor in a mammal. The essential novelty, the essence of the invention, must be described in such details, including proportions and techniques where necessary, as to enable those persons skilled in the art to make and utilize the invention. A broad claim requires a correlatively broad and sufficient disclosure to support it.

Presently, the examples in the instant specification are limited to the preparation of compounds of formula (I) wherein R<sub>1</sub> or R<sub>2</sub> is



Applicants do not provide an adequate written description which provides guidance for the preparation of compounds of formula (I) wherein R<sub>3</sub> or R<sub>4</sub> is an alkyl or alkylene substituted with a

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saccharide. Applicants do not provide an adequate written description which provides guidance for the preparation of compounds of formula (I) wherein  $R_1$  or  $R_2$  is an alkyl or alkylene substituted with a saccharide moiety other than glucose. Applicants do not provide an adequate written description which provides guidance for the use of said compounds for tumor treatment. Examples and description should be of sufficient scope as to justify the scope of the claims. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula. A disclosure involving a new chemical compound or composition must teach persons skilled in the art how to make the compound. The process is considered to be incomplete wherein applicants set forth the preparation of compounds wherein various moieties are left undefined in full, clear and exact terms.

The instant specification invites the skilled artisan to experiment. The factors which must be considered in determining undue experimentation are set forth in *In re Wands*, 8 USPQ2d 1400. The factors include: 1) quantity of experimentation necessary, 2) the amount of guidance presented, 3) the presence or absence of working examples, 4) the nature of the invention, 5) the state of the prior art, 6) the predictability of the art, and 7) the breadth of the claims.

With regard to factors one and two cited above the quantity of experimentation needed to determine the specific chemical formula of the active ingredient, the amount of experimentation needed to determine the amount of an efficacious amount for the treatment of tumors and the time table necessary to achieve efficacious administration

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as well as the specific identity of the said tumors for which the instant invention is applicable would impose an undue burden upon the skilled artisan. There has not been provided adequate guidance in the written description for preparing compounds of formula (I) or using the same commensurate in scope with applicant's claims.

With regard to factors four, five and six, it is noted that there is a great deal of unpredictability in the tumor treatment. The specification provides no evidence that the disclosed compounds in question are able to treat tumors. The specification only hints at how the skilled artisan would assess whether or not a given compound might be able to effectively treat a tumor in a mammal. The guidance provided by the specification amounts to an invitation to the skilled artisan to try and follow the disclosed instructions to make the claimed compounds which might treat tumors broadly. Examples drawn to the synthesis of compounds 1-28 and the data obtained from the cytotoxicity studies of compounds 3, 4, 6, and 9-14 is noted; however, it is seen to be insufficient to provide adequate support for the compounds and method of treatment within the scope of the instant invention.

### ***Conclusion***

5. Claims 1-7 are pending. Claims 1 and 4-7 are rejected. Claims 2-3 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. No claims are allowed.

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6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

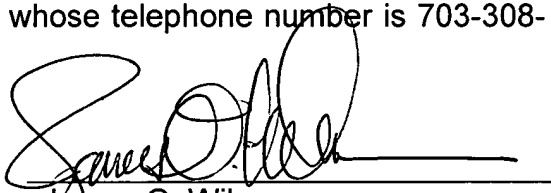
***Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD  
Examiner  
Art Unit 1623



James O. Wilson  
Supervisory Patent Examiner  
Technology Center 1600

ptl  
November 16, 2003